UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION (Both Direct and Indirect Cases)	* * * * * * * * * * *	Civil Action Nos. 1:16-cv-12653-ADB 1:16-cv-12396-ADB

MEMORANDUM AND ORDER ON MOTIONS TO EXCLUDE

BURROUGHS, D.J.

This "pay-for-delay" or "reverse settlement" case arises from an alleged anticompetitive agreement made between the brand and generic manufacturers of Intuniv, an ADHD medication. Defendants Shire LLC and Shire U.S., Inc. (collectively, "Shire") manufacture Intuniv, which is the brand-name for extended release guanfacine hydrochloride. Defendants Actavis Elizabeth LLC, Actavis Holdco US, Inc., and Actavis LLC (collectively, "Actavis" and, together with Shire, "Defendants") manufacture Intuniv's generic counterpart.[1] Plaintiffs, who include both Direct Purchaser Plaintiffs ("DPPs") and Indirect Purchaser Plaintiffs ("IPPs"), allege that they were forced to pay inflated prices for Intuniv due to Defendants' having improperly agreed to delay competition for both brand Intuniv and generic Intuniv in violation of Sections 1 and 2 of The Sherman Act, 15 U.S.C. §§ 1–2. See generally [FWK 140].[2] Presently before the Court are

[1] On August 19, 2020, Actavis informed the Court that it had reached a settlement agreement with the DPPs. [FWK 472]. That settlement does not resolve the Plaintiffs' claims against Shire or the IPPs' claims against Actavis.

[2] For purposes of this memorandum and order, the Court refers to docket entries in FWK, et al. v. Shire, et al., 16-cv-12653 as "FWK [ECF No.]" and docket entries in Picone, et al. v. Shire, et al., 16-cv-12396 as "Picone [ECF No.]."

a number of evidentiary motions seeking to exclude expert testimony concerning Shire's market share, Actavis' likelihood of success in the underlying patent litigation, and the eventual Shire-Actavis agreement. [FWK 296, 297, 298, 299, 329, 331, 333, 335, 337, 339, 341; Picone 246, 248, 250, 252, 254, 256, 258].

I. BACKGROUND

A. Factual Background

On September 2, 2009, the Food and Drug Administration ("FDA") approved a New Drug Application ("NDA") for Shire's brand-name drug, Intuniv. [FWK 343 at 2]. A few months later, on December 29, 2009, Actavis filed an Abbreviated New Drug Application ("ANDA") for its proposed generic version of Intuniv. [Id.]. Several other companies subsequently sought FDA approval to manufacture their own generic alternatives to Intuniv. [FWK 343 at 3]. As the first generic manufacturer to file an ANDA, Actavis would have enjoyed "a 180-day period of exclusivity during which no other generic" manufacturer could have manufactured an Intuniv alternative. In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 543 (1st Cir. 2016). During that exclusivity period, Shire and Actavis would have been the only manufactures approved by the FDA for Intuniv or a generic alternative.

Shire filed suit against Actavis pursuant to 21 U.S.C. § 335(j)(5)(B)(iii), which triggered a 30-month stay of the FDA's approval of Actavis' ANDA for generic Intuniv. See F.T.C. v. Actavis, Inc., 570 U.S. 136, 143 (2013) ("If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court." (citing 21 U.S.C. § 355(j)(5)(B)(iii))). After a bench trial before Judge Andrews in the United States District

Court for the District of Delaware, the 30-month stay of the FDA's consideration of Actavis' ANDA expired and the FDA approved Actavis' generic Intuniv. [FWK 343 at 3].

Before the trial court could issue its opinion, however, Shire and Actavis entered into a settlement agreement. [Id.]. Plaintiffs argue that it appeared likely that the verdict was going to be in Actavis' favor and that the settlement was a reverse payment agreement, which guaranteed Actavis a 180-day exclusivity period in return for its delaying the launch of generic Intuniv until December 1, 2014. [Id.].

B. Procedural History: the DPP Case

FWK Holdings, LLC ("FWK") filed its complaint on December 30, 2016, [FWK No. 1], and Rochester Drug Co-Operative ("RDC") filed similar claims on January 11, 2017. The Court granted a joint motion to consolidate the two actions. [FWK 19].

On September 24, 2019, the Court granted the DPPs' motion to certify the following class:

> All persons or entities in the United States and its territories, or subsets thereof, that purchased Intuniv and/or generic Intuniv in any form directly from Shire or Actavis, including any predecessor or successor of Shire or Actavis, from October 19, 2012 through June 1, 2015 (the "Class").

[FWK 343 at 4, 23]. The Court, however, dismissed FWK as a class representative after finding that the relationship between FWK and class counsel was too entangled. [Id. at 16]. Though the Court had reservations about RDC's adequacy as a class representative, it ultimately agreed that it could serve as class representative. [Id. at 17–18]. On March 12, 2020, RDC filed for bankruptcy under Chapter 11 in the United States Bankruptcy Court for the Western District of New York. See In re Rochester Drug Co-Operative, Inc., No. 20-cv-20230, 2020 WL 4281921 (Bankr. W.D.N.Y. July 24, 2020). Defendants moved to decertify the DPP class, in light of RDC's bankruptcy. [FWK 404]. The Court granted the motion in part and found that RDC

could no longer adequately represent the interests of absent class members due to a conflict of interests arising from its bankruptcy. [FWK 456]. The Court declined to decertify the class, however, and allowed motions to intervene. [Id. at 14–15]. On July 24, 2020, the Court granted a motion to intervene from Meijer, Inc. and Meijer Distribution, Inc. (collectively "Meijer"), a pharmacy retailer headquartered in Michigan and member of the DPP class. [FWK 462]. The parties were granted thirty days of discovery concerning Meijer's adequacy before Meijer may move to be appointed class representative. [Id. at 20].

C. Procedural History: The IPP Case

The IPPs initiated their action on November 23, 2016. [Picone 1]. On August 21, 2019, the Court denied the IPPs' motion to certify two classes of indirect purchasers. [Picone 230]. The IPPs filed a petition with the First Circuit to appeal the Court's decision. The Court of Appeals has not yet ruled on the petition. See generally Picone, et al. v. Shire, No. 19-8023 (1st Cir. 2019).

The IPPs also filed a motion with this Court, requesting that the Court reconsider its denial of class certification. [Picone 235]. Because the motion for reconsideration asked the Court to consider the same issues that were pending before the First Circuit in the interlocutory appeal, and because the Court found that the motion for reconsideration lacked merit, the Court denied the motion. [Picone 276]. The IPPs then filed a motion for leave to file a motion to request that the Court alter its order denying class certification, [Picone 294], which the Court denied, [Picone 325].

II. LEGAL STANDARD

Federal Rule of Evidence 702 provides that a person who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The district court must "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Daubert v. Merrell Dow Pharma., Inc., 509 U.S. 579, 597 (1993). The expert must be "qualified in the specific subject for which [his or her] testimony is offered." Garfield v. Gorilla, Inc., No. 13-cv-12810, 2015 WL 3874826, at *2 (D. Mass. June 23, 2015) (quoting Whiting v. Boston Edison Co., 891 F. Supp. 12, 24 (D. Mass. 1995)). The Court's analysis is "not limited to an appraisal of an expert's credentials and techniques but also entails an examination of his [or her] conclusions to determine whether they flow rationally from the methodology employed." Samaan v. St. Joseph Hosp., 670 F.3d 21, 32 (1st Cir. 2012).

The Court therefore "perform[s] a gatekeeping function by preliminary assessing 'whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts in issue.'" Seahorse Marine Supplies, Inc. v. P.R. Sun Oil Co., 295 F.3d 68, 80 (1st Cir. 2002) (quoting Daubert, 509 U.S. at 592–93). "The ultimate purpose of the Daubert inquiry is to determine whether the testimony of the expert would be helpful to the jury in solving a fact in issue." Hochen v. Bobst

Grp., Inc., 290 F.3d 446, 452 (1st Cir. 2002) (quoting Cipollone v. Yale. Indus. Prod., Inc., 202 F.3d 376, 380 (1st Cir. 2000)).

"When a dispute exists between two experts both of whom use reasonable methods, that dispute 'goes to the weight, not the admissibility of the testimony.'" Koninklijke Philips N.V. v. Zoll Med. Corp., 256 F. Supp. 3d 50, 52 (D. Mass. 2017) (quoting Cummings v. Standard Register Co., 265 F.3d 56, 65 (1st Cir. 2001)).

III. DISCUSSION

The motions to exclude expert testimony fall into three general categories: testimony concerning Shire's market share at the time of the Shire-Actavis lawsuit, opinions regarding Actavis's likelihood of success at the bench trial in the District Court for the District of Delaware, and testimony regarding whether the eventual Shire-Actavis agreement appears to be the result of reasonable arms-length discussions.

A. Expert Testimony Concerning Market Share

"[A] reverse payment typically arises where a brand-name drug manufacturer pays the generic manufacturer to delay entry of its generic equivalent, thereby protecting the brand's market from generic competition." In re Loestrin, 814 F.3d at 542. "Market power is the ability to raise price profitably by *restricting output*." Ohio v. Am. Express Co., 138 S. Ct. 2274, 2288 (2018) (emphasis in original) (quoting P. Areeda & H. Hovenkamp, Fundamentals of Antitrust Law § 5.01 (4th ed. 2017)). The leading case outlining the product market analysis is United States v. E.I. du Pont de Nemeours & Co., 351 U.S. 377 (1956). In that case, the government relied on du Pont's production of almost seventy-five percent of the cellophane sold in the United States to establish that du Pont had monopoly power. Id. at 379. Du Pont argued that cellophane was not a separate market, as it competed with other flexible packaging materials, including aluminum foil, wax paper, saran wrap, and polyethylene. Id. at 380. In determining

the relevant market, the Supreme Court called for "an appraisal of the 'cross-elasticity' of demand in the trade" to determine whether the "commodities [were] reasonably interchangeable by consumers for the same purpose." Id. at 394–95. The Court divided that analysis into three considerations: the quality of cellophane, determining whether the attributes of cellophane were sufficiently similar with other products; the functional interchangeability of cellophane; and cross-elasticity of demand between products by looking at how sales of one product respond to price changes in the other. Id. at 400–01; see also Zschaler v. Claneil Enters., 958 F. Supp. 929, 941 (D. Vt. 1997) ("A relevant market consists of 'products [or services] that have reasonable interchangeability for the purposes for which they are produced—price, use, and qualities considered." (alteration in original) (quoting E.I. Du Pont, 351 U.S. at 404)). "If a slight decrease in the price of cellophane cause[d] a considerable number of customers of other flexible wrappings to switch to cellophane, it would be an indication that a high cross-elasticity of demand exists between them; that the products compete in the same market." E.I. du Pont, 351 U.S. at 400.

"Market power can be shown through two types of proof. A plaintiff can either show direct evidence of market power (perhaps by showing actual supracompetitive prices and restricted output) or circumstantial evidence of market power." Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196–97 (1st Cir. 1996) (citing Rebel Oil Co. v. Alt. Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995)). Circumstantial evidence might include cross-price elasticity as well as functional interchangeability, In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 563144 at *5–10 (D. Mass. Jan. 25, 2018). "The market is established by examining both the substitutes that a consumer might employ and 'the extent to which consumers will change their consumption of one product in

response to a price change in another, i.e., the cross-elasticity of demand.'" Flovac v. Airvac, 817 F.3d 849, 854 (1st Cir. 2016) (quoting Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 469 (1992)). "Where direct evidence of market power is available . . . a plaintiff need not attempt to define the relevant market." In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 3d 367, 388 n.19 (D. Mass. 2013).

1. Motion to Exclude in Part the Testimony of Dr. Gregory Bell

The DPPs moved to exclude the testimony of Dr. Gregory Bell ("Bell"), [FWK 296], and the IPPs subsequently joined the motion, [Picone 237]. Bell leads the global life sciences practices at an economics and management consulting firm, where he "focus[es] on the economics of business strategy, working with firms to develop sustainable competitive advantages in specific product markets." [FWK 301-82 at 54].

Plaintiffs move to strike Bell's opinion on market power, including paragraphs 16–69 of his May 31, 2019 report, paragraphs 10–57 of his July 12, 2019 report, and any related testimony. [FWK 296 at 1]. The Plaintiffs argue that Bell ignores direct evidence that Shire possessed market power, cherry-picks indirect evidence without examining cross-price elasticity, and, as an economist, is unqualified to testify regarding Intuniv's interchangeability with other drugs. [FWK 305 at 6].

Bell found that the relevant market for purposes of this case includes other non-stimulant drugs used to treat ADHD and that Intuniv's share of that market at the time of the alleged anticompetitive agreement was no more than 27.5%. [FWK 301-82 ¶ 6]. Plaintiffs argue that Bell failed to consider direct evidence of market power, because he did not consider Shire's profit margins, and that he did not consider price elasticity, instead electing to consider product interchangeability. [FWK 305 at 8].

"Direct evidence of market power may include evidence of 'actual supracompetitive princes and restricted output.'" Solodyn, 2018 WL 563144, at *10 (quoting Coastal Fuels, 79 F.3d at 196). Though Bell notes Shire's high gross profit margins for Intuniv, he argues that high profit margins are to be expected in pharmaceutical cases such as this, due to incentives within the pharmaceutical market that make it so that a pharmaceutical may have little market power despite its high profit margins. [FWK 301-82 ¶¶ 54–58]. Bell therefore does not fail to consider the evidence of direct power, as Plaintiffs argue, but instead offers testimony as to why, in a pharmaceutical case, marginal cost may not be as probative of market power as in other cases. Such testimony is clearly permissible. See, e.g. Solodyn, 2018 WL 563144, at *10–11 (considering expert testimony that marginal cost was not as probative in pharmaceutical cases because it "ignore[s] the high fixed or sunk costs prevalent in innovation-intensive industries such as the pharmaceutical industry" (internal quotation marks omitted)); In re Asacol Antitrust Litig., 323 F.R.D. 451, 484 (D. Mass. 2017) ("In the market for a product with high fixed costs, evidence that prices routinely exceed marginal costs may not necessarily be evidence that prices are supracompetitive, because even competitive prices may exceed marginal cost.").

Plaintiffs next argue that Bell does not analyze the cross-price elasticity of demand between Intuniv and other products. [FWK 305 at 12]. Bell claims that market share should instead be determined by examining "the reasonable interchangeability of use." [FWK 301-82 ¶ 19]. Therapeutic interchangeability is circumstantial evidence of the relevant market. Solodyn, 2018 WL 563144, at *5. Bell claims to arrive at a representation of therapeutic interchangeability by reviewing "[c]linical guidelines, formulary decisions, and physician prescribing behavior." [FWK 301-82 ¶ 22]. For example, Bell considers formulary competition, which tracks the rebate payments made by drug manufacturers to health plans in order to receive

a favorable placement on the plan's formulary. [Id. at ¶ 30]. Internal documents further evidence that Shire sought to increase its share of the "Non-Stim Adjunct Market," or the market where non-stimulant ADHD medications are prescribed in addition to a stimulant. [Id. at 15]. Such expert evidence has previously been found credible. In FTC v. Abbvie, for example, the court found that the relevant market should not be limited to the brand and generic versions of a drug, but should include all testosterone replacement therapy treatments based on price competition within that treatment market, including using rebates, promotional expenses, and internal documents that showed that the company viewed itself as competing with the other treatments. 329 F. Supp. 3d at 131–32.

But, even if a product is "functionally interchangeable with other branded products, . . . circumstantial evidence of market definition also requires a showing of *economic* interchangeability with these therapeutic alternatives." Solodyn, 2018 WL 563144, at *6 (first citing Flovac, 817 F.3d at 854; then citing United Food and Comm. Workers Local 1776 v. Teikoku Pharma. USA (In re Lidoderm), 296 F.Supp.3d 1142 (N.D. Cal. 2017)); see also ABA Model Jury Instructions in Civil Antitrust Cases at A-108 n.2 (2016) ("In assessing whether products are within the relevant market, the jury must consider not only whether the products are functionally similar but also whether the products are economically interchangeable. That is, there must be cross-price elasticity of demand . . . ."). Cross-price elasticity measures "the substitutability of products" by gauging the "responsiveness of the demand for one product to changes in the price of a different product." Mylan Pharma., 838 F.3d at 437.

Bell analyzed the percentage of utilization among non-stimulants and found that, as the price for Intuniv lowered, Shire's market share increased in the non-stimulant market. [FWK

360 at 16]. Bell demonstrated that his methods concerning interchangeability are reliable and that he is qualified to offer testimony on this topic.

> That [the defense expert] uses a different economic analysis, one that explicitly considers the changes in effective pricing (i.e., accounting for coupons, discounts and rebates) does not mean that such analysis fails to bear upon a showing of cross-elasticity of demand. Whether, when weighed against [the plaintiff experts'] demand models, such analysis will carry the day as a matter of fact is for the jury to decide.

Solodyn, 2018 WL 563144, at *9.

Finally, Plaintiffs argue that, even if therapeutic interchangeability were the relevant test when determining market share, Bell, as an economist, is unqualified to make the medical determination of whether two drugs are in fact interchangeable. [ECF No. 305 at 16–17]. Defendants argue that Bell's analysis closely adheres to methods used by economists in other cases and that his opinions do not rest on medical views, but on objective data regarding the interchangeability of Intuniv for other products. [ECF No. 360-1 at 19]. The Court agrees with the Defendants. Although Plaintiffs are free to question Bell as to how he analyzed the circumstantial evidence of market power, it is clear that his analysis depends on a reliable and accepted method. To the extent that he attempts to opine concerning the medical utility of Intuniv as compared to other ADHD treatments, such testimony will be excluded. He is free, however, to rely on his economic expertise and the evidence before him to offer an opinion as to whether Intuniv is economically interchangeable with other ADHD treatments. The motion to exclude Bell, [FWK 296], is therefore DENIED.

2. Motion to Exclude Martha Starr and Christopher Baum

Defendants move to exclude testimony from Plaintiffs' Experts Matha Starr ("Starr") and Christopher Baum ("Baum"). [FWK 331; Picone 248]. Starr and Baum both offer opinions to the effect that the relevant market in this case is exclusively Intuniv and generic versions of

Intuniv, as opposed to all non-stimulant ADHD medications. Starr is a senior economist at Greylock McKinnon Associates and was previously an economics professor at American University. [FWK 325-56 ¶ 1]. Baum is a professor of economics and social work at Boston College. [FWK 325-189 ¶ 1].

First, Defendants argue that Starr's analysis of price improperly assumes that, because sales of guanfacine ER increased after generics entered the market, Shire must have been restricting output. [FWK 310 at 10]. Defendants assert that Starr failed to conduct any analysis concerning how the increase in prescriptions was directly related to generics entering the market. [Id.]. Plaintiffs respond that Starr's findings are not simply based on the increase in sales after generics entered the market, but also on Shire's high profit margins. [FWK 354-1 at 10–11]. Although "[a]bsent any evidence of restricted output, . . . evidence of high margins is insufficient direct evidence as a matter of law to demonstrate market power," Solodyn, 2018 WL 563144, at *12, Plaintiff's evidentiary burden does not require that Starr herself provide an explanation of restricted out. Further, Starr does analyze the rate of Intuniv prescriptions before and after generic options became available. [FWK 325-66 ¶ 72]; see also [FWK 325-92 ¶¶ 32–35]. Therefore, Defendants' argument goes to the weight that should be afforded Starr's testimony, not its admissibility. Defendants will be free to challenge Starr's methodology on cross examination, but her analysis is sufficient to survive the motion to exclude on this issue.

Second, Defendants argue that Starr's opinion about indirect evidence of market power, which relies on price, should also be excluded because it is based on incomplete data in that it does not rely on what consumers actually paid. [FWK 310 at 11–14]. Dr. Starr admits that "the full price of a drug to those who pay for it—consumers and private and public health-plan sponsors—is the retail price of the drug, net of various rebates, discounts, chargebacks, and

returns. The wholesale price . . . does not net out rebates or discounts applied at the retail level." [FWK 325-56 ¶ 43]. She similarly did not find the actual out-of-pocket cost of the other ADHD drugs she evaluated. [FWK 310 at 15]. Instead, Starr relied on data from IQVIA (formerly IMS Health), which track quantities and prices of drugs at wholesale and retail levels, including IQVIA's National Sales Perspective and National Prescription Audit databases, to measure the wholesale price per prescription and monthly total prescriptions of Intuniv. [Id.]. She then engaged in two "natural experiments" with the data. First, she considered the effect of a decline in price for generic guanfacine ER on the demand for other ADHD medications. [FWK 325-56 ¶¶ 83–89]. Next, she similarly analyzed the effects of a price decrease on a different ADHD medication. [Id. ¶¶ 90–91]. But, as Defendants note, her experiments could not determine the actual price that consumers paid. [FWK 310 at 16].

Similarly, Baum, on whose opinion Starr relies, used the IQVIA data sets to determine "cross-price elasticities between Intuniv and the potential therapeutic alternatives to Intuniv that were identified by Dr. Starr." [FWK 325-189 ¶¶ 9–10]. Like Starr, Baum admits in his rebuttal report that the data "do[es] not reflect the off-invoice discounts and rebates separately paid to insurers, or other price concessions paid to patients or other health system participants." [FWK 325-190 ¶ 11].

Plaintiffs maintain that similar testimony has been found appropriate in the First Circuit. [FWK 354-1 at 11–12 (citing In re Asacol Antitrust Litig., No. 15-cv-12730, ECF No. 563 at 28–29 (D. Mass. Nov. 9, 2017)]. Further, though Starr did not analyze the actual out-of-pocket costs, she did include Shire's rebates in her analysis of market power. [FWK 325-56 ¶ 66 ("[I]n the year before the first generic version of guanfacine ER entered, Shire paid rebates amounting to [redacted] of Intuniv's gross sales; assuming this is also the amount by which Intuniv's average

wholesale price overstated a wholesale-price equivalent that accounts for rebates, the latter price would be [redacted] per pill rather than the actual wholesale price of $9.39. But in both cases, the decline to a price of [redacted] per pill in the first year after generic entry is dramatic: an [redacted] decline from a price of [redacted] and [redacted] decline from a price of $9.39. A price decrease exceeding [redacted] in one year (with further declines thereafter) clearly indicates that Shire had substantial market power with respect to Intuniv before generic entry.")].

The Court finds that, though Starr and Baum did not rely on the actual out-of-pocket costs paid for Intuniv, their testimony is sufficiently probative and reliable to be admissible. In Solodyn, for example, the court found that cross-elasticity testimony based on IQVIA data was sufficiently supported to be admissible, and that the opposing party could challenge the report by "relying upon the opinion of their own expert . . . , vigorous cross-examination, and other traditional methods." 2018 WL 563144, at *7. The same is true here. Defendants are free to challenge the weight of Baum and Starr's analysis on cross examination.

Third, Defendants argue that Starr should not be applying the DOJ/FTC's Hypothetical Monopolist Test in this case, because it does not involve a merger. [FWK 310 at 19]. Under that test the DOJ considers

> what would happen if a hypothetical monopolist of that product imposed at least a "small but significant and nontransitory" increase in price, but the terms of sale of all other products remained constant. If, in response to the price increase, the reduction in sales of the product would be large enough that a hypothetical monopolist would not find it profitable to impose such an increase in price, then the Agency will add to the product group the product that is the next-best substitute for the merging firm's product . . . . This process will continue until a group of products is identified such that a hypothetical monopolist over that group would profitability impose at least a "small but significant and nontransitory" increase. . . . The Agency generally will consider the relevant product market to be the smallest group of products that satisfies this test.

DOJ and FTC, Horizontal Merger Guidelines, §1.11 (rev. Apr. 8, 1997); see also DOJ and FTC, Horizontal Merger Guidelines § 4.1.1 (rev. August 19, 2010) (explaining the Hypothetical Monopolist Test).

The Eastern District of Pennsylvania has recently found that the Hypothetical Monopolist Test is inappropriate in a non-merger pharmaceutical antitrust case, due to the unique pricing practices in the pharmaceutical industry including rebates and discounts. See AbbVie, 329 F. Supp. 3d at 129. "[A]pplication of the [test] would result in a market limited to a brand-name drug and its AB-rated generic in almost every instance." Id. at 130. But, other courts have not yet endorsed that court's reasoning and, in the First Circuit, it remains true that "the hypothetical monopolist test is the 'touchstone of market definition,' even in contexts outside of horizonal mergers." Asacol, 323 F.R.D. at 471 (citation omitted), rev'd on other grounds 907 F.3d 42 (1st Cir. 2018); see also Coastal Fuels, 79 F.3d at 198 ("The touchstone of market definition is whether a hypothetical monopolist could raise prices."). Defendants are free to question Starr's use of the hypothetical monopolist test during cross-examination, but her opinion is well-supported and reliable and therefore will not be excluded.

The motions to exclude Starr and Baum, [FWK 331; Picone 248], are therefore DENIED.

3. Motion to Exclude in Part the Testimony of Thomas Fernandez, M.D.

Lastly, Defendants move to exclude certain opinions of Plaintiffs' expert Thomas Fernandez, M.D. ("Fernandez"). [FWK 341; Picone 258]. Fernandez is co-director of the Tic Disorder/OCD/ADHD Specialty Clinic at the Yale Child Study Center. [FWK 325-184 ¶¶ 12–13]. In discussing Shire's alleged market share, Fernandez believes that Intuniv was not "therapeutically interchangeable" with other non-stimulant ADHD medications and that his

prescribing habits are consistent with those of most of his professional colleagues across the country.

First, Defendants seek to exclude Fernandez's opinion that Intuniv is not "therapeutically interchangeable" with other ADHD treatments because he does not define the term. [Picone 259-1 at 6]. During his deposition, Fernanez said that "therapeutic interchangeability" meant that one drug could be "freely substituted [for another] and have the same effect" so that "you could close your eyes, pick one at random, and you would be fine in doing it that way." [Id. at 7 (quoting FWK 325-183 at 65)]. Defendants argue that it is unclear that the "concept of a drug being 'therapeutically interchangeable' is even considered in defining a relevant product market. In fact, the relevant legal inquiries focus on whether the products are 'functionally similar,' economically interchangeable, or have some 'reasonable interchangeability.'" [Id. (emphasis omitted)].

In Solodyn, Judge Casper allowed the plaintiffs' medical expert to testify as to the therapeutic interchangeability of the drug with other acne medications. 2018 WL 563144, at *5 n.8 ("[Plaintiff's expert's] definition of therapeutic interchangeability may differ from Defendants' definition, but it is relevant to the jury and grounded in her medical experience along with the documents and medical literature she relied upon in rendering her opinion."). Though Plaintiffs argue that cross-price elasticity is the primary factor in determining market power, they assert that if the Court considers evidence of treatment similarity then "Fernandez's therapeutic interchangeability opinion is relevant and admissible expert evidence, and should be allowed to rebut the defendants' claims that Intuniv is therapeutically interchangeable with drugs other than its AB-rated generics." [FWK 351-1 at 10]. Because testimony concerning interchangeability is circumstantial evidence of market power, the Court will not exclude such

testimony. Defendants are free to challenge the weight of Fernandez's testimony on cross examination.

Second, Fernandez claims that his "prescribing habits for ADHD are generally consistent with those of most colleagues in the field of child and adolescent psychiatry," [FWK 325-184 ¶ 89], and that "most physicians are similarly unaware [as he is] of the various drugs' pricing and insurance coverage," [FWK 325-185 ¶ 17]. Defendants argue that Fernandez should not be permitted to reference the prescribing habits of his colleagues nationwide, including whether prescribers are generally aware of pricing and insurance coverage, when he has not taken any steps to determine what those habits are. [FWK 259-1 at 8]. Fernandez bases his opinion on conversations with his coworkers, teaching residents and fellows, and colleagues at national conventions. [FWK 325-183 at 71–73]. It is clear that Fernandez's testimony is meant to support the weight of his opinion, and that he is not seeking to make specific representations about how his colleagues prescribe. Though Fernandez is free to testify that his prescribing habits are generally consistent with those of his colleagues, as support for his own testimony, he is not permitted to testify as to his colleagues' prescribing rates more specifically. Defendants are free to challenge Fernandez's opinion during cross-examination, but it is sufficiently reliable to be admitted.

The motions to exclude Fernandez's testimony, [FWK 341; Picone 258], are therefore DENIED.

B. Expert Testimony Concerning Likelihood of Success at Trial

In support of their claims, Plaintiffs have argued that it appeared likely that Actavis would succeed in the underlying patent litigation such that, but for Shire and Actavis's eventual settlement, a generic version of Intuniv would have been on the market sooner and Plaintiffs

would not have paid an inflated price for brand Intuniv. Both parties have therefore disclosed experts that will testify as to the likely outcome in the underlying litigation.

1. Motion to Exclude in Part the Testimony of Dr. Alexander Klibanov

The DPPs move to exclude part of the testimony of Shire's expert Professor Alexander Klibanov ("Klibanov"). [FWK 297]. Specifically, the DPPs want to strike Klibanov's statements regarding Intuniv's commercial success, including paragraphs 218,[3] 219,[4] and 222[5] of his report. [Id. at 1]. The IPPs subsequently moved to join the motion. [Picone 237]. Klibanov is a chemistry professor at the Massachusetts Institute of Technology. [FWK 301-99 ¶ 12]. He seeks to opine on the merits of the original patent litigation between Shire and Actavis in response to expert reports from Plaintiffs' experts Drs. Mansoor Amiji ("Amiji") and Michael

[3] "Shire presented evidence with respect to several indicia of non-obviousness, e.g., commercial success and copying. I understand that the former can be a particularly important secondary consideration of non-obviousness; although I am not an economist, having reviewed Shire's materials pertaining to commercial success (outlined in the next paragraph), it seems that this evidence would have helped Shire's non-obviousness case." [FWK 301-99 ¶ 218].

[4] "According to the trial testimony of Matthew Pauls, Vice President of Global Commercial Operations for Shire Regenerative Medicine, Shire's gross sales for Intuniv had doubled between 2010 and 2012, and significantly outpaced the growth of the overall U.S. anti-ADHD market. By 2012, the year of the trial in the Intuniv Patent Litigation, Intuniv was on pace to earn more than $500 million in annual gross sales and was one of the top 200 drugs in terms of sales overall in the U.S. market. Mr. Pauls called Intuniv's sales 'remarkable' and testified that Intuniv was 'without question' a commercial success. Dr. Rausser, Shire's expert economist testified that commercial success was not 'a close call,' i.e., undeniable. Shire argued that Intuniv had become more popular than Strattera, a competing non-stimulant anti-ADHD drug product, despite Strattera's seven-year first-mover advantage. Actavis countered that Intuniv's commercial success was due to marketing efforts, rather than owing to the patented invention." [FWK 301-99 ¶ 219].

[5] "In my opinion, the evidence presented at trial suggests that Actavis tried to copy the Intuniv formulation because of the latter's superior and innovative sustained-release profile and that at least some of the commercial success of Intuniv must be due to its superior and innovative sustained-release profile." [FWK 301-99 ¶ 222].

Cima ("Cima"). [FWK 301-99 ¶ 2–3]. Plaintiffs argue that, as a chemist, Klibanov is not qualified to opine on Intuniv's commercial success. [FWK 306 at 9].

Plaintiffs allege that Klibanov impermissibly seeks to testify as to Shire's commercial success as part of his testimony concerning the non-obviousness of Shire's patents. [FWK 306 at 7]. During the Shire-Actavis lawsuit, Actavis argued that Shire's Intuniv patent was invalid as obvious. [FWK 362-1 at 7; FWK 301-99 ¶ 203]. Klibanov would opine that "Actavis would not have prevailed on obviousness, especially with respect to claim 6 of the '599 patent and claims 3 and 8 of the '794 patent." [FWK 301-99 ¶ 224 (emphasis omitted)]. In assessing the obviousness of a patent claim, courts must consider "(1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations, including *commercial success*, long felt but unsolved needs, failure of others, copying, and unexpected results." Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd., No. 17-cv-11008, 2018 WL 10910845, at *4 (D. Mass. Jul. 30, 2018) (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17–18 (1966)). "Such secondary considerations as *commercial success*, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Graham, 383 U.S. at 17–18 (emphasis added). Defendants argue that Klibanov is not analyzing Intuniv's economic success, but is instead offer a "comprehensive assessment of the nonobviousness/validity of Shire's Intuniv patents . . . —an exercise that is indisputably required under Supreme [C]ourt and Federal Circuit authority." [FWK 362-1 at 4]. Therefore, Defendants argue, Klibanov may testify as to how his technical nonobviousness analysis is consistent with the trial testimony concerning commercial success. [FWK 362-1 at 10].

The Northern District of California has found that a technical expert could not testify as to commercial success, including that the inventions "ha[d] been very successful" or had led "to the commercial success of products using the inventions," even if he was otherwise qualified to offer technical expertise. Rambus Inc. v. Hynix Semiconductor, Inc., 254 F.R.D. 597, 605 (N.D. Cal. 2008). In that case, the court found that the technical expert "lack[ed] the expertise to explain whether or not advertising, standardization, import laws, contractual relationships, or any of a number of other factors influenced the commercial success of" the product. Id. at 604; see also Wonderland Nurserygoods Co., Ltd. v. Thorley Indus. LLC, No. 13-cv-00387, 2015 WL 5021416, at *13 (W.D. Pa. Aug. 21, 2015) (excluding the testimony of a product design expert concerning commercial success in a patent case because, though he had expertise in product design and manufacturing, he lacked expertise in finance).

In this case, however, Klibanov does not seek to offer his own economic expertise, but relies on the expert report of Dr. Gordon Rausser, which was produced in the original Shire/Actavis lawsuit. [FWK 301-99 ¶ 219]. "Experts routinely rely upon other experts hired by the party they represent for expertise outside of their field." Apple Inc. v. Motorola, Inc., 757 F.3d 1286, 1321 (Fed. Cir. 2014). However,

> [a] witness who has no relevant expertise or familiarity with a subject may not . . . simply parrot the conclusions of an expert who does. At a minimum, to allow such testimony would effectively permit a party to evade the disclosure requirements of Rule 26 and would preclude meaningful cross-examination.

Carrozza v. CVS Pharm., Inc., 391 F. Supp. 3d 136, 145 (D. Mass. 2019).

Here, Klibanov would be testifying as to the opinions of another expert, who would be unavailable for cross-examination. Klibanov's testimony as to commercial success must therefore be excluded. To the extent that Klibanov attempts to speak to commercial success based on his own technical expertise, he is unqualified to do so, and to the extent that Klibanov

relies on the findings of other experts in the earlier Shire-Actavis litigation, such experts are unavailable for cross-examination in this case. "Although experts may testify as to the things on which they rely, experts cannot bolster or corroborate their opinions with the opinions of other experts who do not testify because such testimony improperly permits one expert to become a conduit for the opinion of another expert, who is not subject to cross-examination." Handbook of Fed. Evid., § 703:1 (Nov. 2019) (internal citations and alterations omitted). The motion to exclude, [FWK 297], is therefore GRANTED as to paragraphs 218, 219, and 222 of Kliabnov's report.

2. Motion to Exclude John Thomas

Defendants next move to exclude the testimony of Plaintiffs' expert John Thomas ("Thomas"). [FWK 333; Picone 250]. Thomas is a professor of law at Georgetown and has served as an instructor at the U.S. Patent and Trademark Office Patent Academy. [FWK 325-45 ¶¶ 2–3]. Thomas believes that Actavis had a greater than 95%chance of ultimately prevailing in the underlying Shire-Actavis lawsuit and that a decision on the merits was "imminent" when the parties settled.

a. Thomas' Testimony That Actavis Had a 95% Chance of Succeeding on the Merits

Defendants first argue that Thomas' 95% statistic is not based on any methodology. [FWK 314 at 5]. In support, Defendants argue that Judge Andrews had previously denied Actavis's motion for summary judgment and that analysts were split as to who would prevail at trial. [Id. at 9–10]. Although Thomas "concludes with a high degree of professional certainty that Shire had virtually no chance—that is to say, at best a 5% chance—of successfully asserting its patent against Actavis," [FWK 325-45 ¶ 73], he provides no explanation for how he arrived at this figure, other than generally claiming that he reviewed the complete litigation record. [Id.

¶ 74]. For example, during his deposition, Thomas explained that he had relied on his previous work experience and expertise, and then also said that he had not used any kind of formula to arrive at the 95% estimate. [FWK 325-195 at 225 ("I used quantitative inputs, but I didn't use a formula or equation. I just relied upon my experience and the sorts of factors that I've described at some length just now."); [Id. at 223–24 (listing those factors, which predominantly reference his previous experience)].

The Court must not only ensure that an expert is qualified to give an opinion, but that the opinion is based on "more than subjective belief or unsupported speculation. . . . Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." Daubert, 509 U.S. at 590. Courts therefore exclude "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). "No amount of expertise can turn speculative or untestable theories into admissible expert testimony." United States ex rel. Banigan v. Organon USA Inc., No. 07-cv-12153, 2015 WL 10002943, at *2 (D. Mass. Aug. 17, 2015). The expert must provide a "bridge from [the expert's] experience to his conclusions." Ankuda v. R.N. Fish & Son, Inc., 535 F. Supp. 2d 170, 174 (D. Me. 2008).

As the Southern District of New York has noted, "testimony by experienced lawyers about the likelihood that patent litigations will succeed or not succeed has been admitted in several post-Actavis reverse-payment cases." In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 188 (S.D.N.Y. 2018) (collecting cases). Courts have allowed experts to consider an agreed-upon settlement and the parties' projected profits in order to arrive at an estimate of *what the parties likely thought* their likelihood of success on the merits would be at trial, not an objective estimate of who would have actually succeeded. See Lidoderm, 296 F.

Supp. 3d at 1186–87. An expert may also be permitted to offer a specific estimate of the likelihood of success in an underlying trial if she relies on a sufficiently testable methodology. In Androgel, for example, the expert at issue began with the average win-rate of a plaintiff in a Hatch-Waxman case and then analyzed the case to find that it was weaker than average, and discounted the average projection to represent the likelihood of their success. No. 09-md-02084, 2018 WL 2984873, at *6–7 (N.D. Ga. June 14, 2018).

Though Judge Casper previously allowed Thomas to offer similar testimony, Solodyn, 2018 WL 563144, at *16, Defendants argue that, because the parties in that case did not challenge Thomas' methodology, Judge Casper never considered the issue. In Solodyn,, Thomas opined that a brand company would have had "a virtually zero percent chance (*i.e.*, less than 5 percent) of prevailing against any of the generic companies" in the underlying action. Id. Outside of this district, courts have permitted similar testimony so long as it was based on experience in patent law, examination of the underlying patent litigation record, and a review of the reports of other technical experts in the case at hand. See [FWK 356-1 at 10 n.27 (listing cases)]. Defendants argue that many of those cases also did not involve a challenge to the methodology underlying the opinion. [FWK 379-1 at 8]; see Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 767 (E.D. Pa. 2015) (permitting expert to testify that generic company had an 80% chance of prevailing in underlying litigation), aff'd 868 F.3d 132 (3d Cir. 2017).

The Court joins those courts, including a court in this district, that have permitted lawyers to testify as experts on the likelihood of success on the merits in a case underlying a reverse-payment litigation. See, e.g., In re Loestrin 24 Fe Antitrust Litig., 433 F. Supp. 3d 274, 306 (D.R.I. 2019) (permitting an expert to testify that generic company had a 90% likelihood of success on the merits in underlying litigation). Thomas has not, however, provided a

methodology for how he arrived at this 95% figure, a finding which was not challenged in Solodyn. Therefore, the Court will permit Thomas to testify as to his professional opinion that Shire would not have prevailed in the underlying litigation, but he will not be permitted to provide any specific percentage of likelihood, as he has provided no concrete methodology for how he reached this figure.

Defendants also argue that Thomas cannot be sure that Judge Andrews' decision would have been upheld on a potential appeal, because of a split among the district courts. Before trial, the parties strongly disputed the proper construction of a claim element in the patent before Judge Andrews. In the end, Judge Andrews agreed with Actavis's argument. Thomas assumes that this decision would have been upheld on appeal before the Federal Circuit. But, Defendants argue that, at the same time that Judge Andrews adopted Actavis's argument, courts in the Northern District of California and the District of Colorado rejected Actavis's position and it is thus possible that Judge Andrew's decision would have been overturned on appeal . See Shire LLC, et al. v. Impax Labs, Inc., et al., No. 10-cv-05467, 2012 WL 1980803 (N.D. Cal. June 1, 2012); Shire LLC, et al. v. Sandoz Inc., No. 11-cv-01110, 2012 WL 5494944 (D. Colo. Nov. 13, 2012). This challenge too goes to the weight of the testimony rather than admissibility and the issue may be aired through cross-examination.

b. Thomas' Testimony Concerning the Timing of Judge Andrews' Decision

Second, Defendants argue that Thomas' opinion as to the timing of a decision in the Shire-Actavis lawsuit is wholly speculative. "In [Thomas'] professional opinion, a ruling from Judge Andrews of invalidity and noninfringement was imminent at the time Shire and Actavis entered into their settlement agreement on April 25, 2013, nearly six months after the completion of post-trial briefing." [FWK 325-45 ¶ 114]. Thomas bases this estimate on a review of Hatch-

Waxman cases that were tried before Judge Andrews, which showed that Judge Andrews issued final judgment, on average, 5.3 months after the completion of post-trial briefing. [Id. ¶¶ 115–17]. This opinion is corroborated, Thomas argues, by estimates from Shire, Teva Pharmaceuticals (with whom Shire settled separately in the consolidated action), and analysts at the time. [Id. ¶¶ 118–19]. Thomas' analysis takes no account of the number of claims at issue in each case or the complexity of the different patents at issue.

Defendants argue that, even if Thomas' methodology were sound, it conflicts with the actual timeline of Judge Andrews' decision-making in this case. [FWK 314]. One month after Shire settled with Actavis, Shire settled with another defendant in the consolidated action before Judge Andrews. [FWK 314 at 10–11]. At that point, Judge Andrews had not yet reached a decision on the merits. Even in Solodyn, Judge Casper did not allow Thomas's testimony concerning the likely timing of a decision, because it was inconsistent with the timelines in other Solodyn patent cases. Solodyn, 2018 WL 563144, at *16. In this case, Thomas' testimony conflicts with the timeline in the very case at issue, which is more telling than whether his testimony conflicts with other Intuniv cases. Therefore, the Court finds that Thomas' opinion concerning the timing of Judge Andrews' opinion must be excluded.

Finally, Defendants argue that Thomas' opinion should be excluded because he relied on the conclusions of Plaintiffs' experts Amiji and Cima. [FWK 314 at 18]. This argument is considered below in the context of the motions to exclude the testimony of Amiji and Cima.

The motions to exclude Thomas's testimony, [FWK 333; Picone 250], are therefore GRANTED in part and DENIED in part.

3. Motions to Exclude Mansoor Amiji, R.Ph., Ph.D., and Michael Cima, Ph.D.

Defendants next move to exclude the testimony of Plaintiffs' experts Amiji and Cima, which concerns the infringement and validity of Shire's patents. [FWK 337; Picone 254]. Defendants argue that their opinions that Shire's patents were not infringed and were invalid is based on information that was not before the trial court and therefore cannot be considered in evaluating either whether Judge Andrews or the Federal Circuit would have found Shire's patents valid and infringed or whether Actavis was likely to succeed at trial. [Picone 255-1 at 5, 6]. Plaintiffs argue that the testimony is relevant because it "will aid the jury in evaluating the invalidity claims at issue in the patent case" and "are offered to bolster the plaintiffs' position that Actavis could have prevailed in the patent litigation." [FWK 350-1 at 3, 6].

Amiji has acknowledged that he relied on materials that were outside of the record before Judge Andrews when considering the underlying patent litigation. See [FWK 325-177 ¶ 4]. Amiji contrasts his own testimony with that of Defendants' expert Klibanov, who "was asked 'to evaluate the strength of Shire's infringement . . . case and Actavis'[] non-infringement . . . defenses in the Intuniv Patent Litigation based solely on the information (evidence, testimony, briefing, etc.) presented to Judge Andrews during the 2012 Intuniv Patent Litigation,' and 'limited [his] own analysis of the Intuniv Patent Litigation . . . to the trial record . . . .'" [Id.]. Amiji "*in contrast*, was asked to give [his] opinion on whether, *as an objective, scientific matter*, the Actavis ANDA product infringed the asserted claims of the '599 and '794 patents and whether Shire demonstrated, as a scientific matter, that the Actavis ANDA product infringed the asserted claims." [Id. (emphasis added)]; see also [FWK 325-177 ¶ 6 ("My opinion remains that, whether limited to the litigation record as Dr. Klibanov views it or encompassing the expert reports and other materials before the court prior to trial, Shire failed to show that the fumaric

acid in Actavis's ANDA satisfies or functions as element (c) . . . . My opinion also remains that the scientific evidence, including the evidence presented by Actavis at trial, demonstrates that fumaric acid does not function as or satisfy element (c) of the claims.")].

Plaintiffs argue that, even if the information was not before the trial court, other courts have found such testimony permissible to provide context for the technology at issue. [FWK 350-1 at 14]. The Northern District of California, for example, declined to exclude testimony as to the likelihood of success in an underlying litigation, despite the fact that the expert relied on information outside of the trial court record. Lidoderm, 296 F. Supp. 3d at 1186. In that case, the court found that it was permissible for the expert to rely on references outside of the trial record "to explain the context for the technology at issue . . . , given [the expert's] clear statement that these additional references did not impact his opinions as to" the underlying litigation. Id. Even that court noted, however, that the expert had not "relied upon" information outside of the record in forming his opinion. Id. This Court concludes that, if the experts relied on information outside of the record as a basis for reaching their opinions, they must be excluded.

Defendants provide a list of twenty-one sources that Amiji considered that were not properly before Judge Andrews at the time of the Shire-Actavis patent trial. [Picone 255-1 at 9–10]. Though Plaintiffs admit that Amiji referenced five non-record documents to support his substantive positions in the report, they maintain that he only relied on material before the trial court. See [FWK 350-1 at 9, 21 ("Prof. Cima's opinions rely entirely on evidence from the trial record. . . . There are only five documents on the list of 21 [sources that were not included in the trial record] that Prof. Amiji relies on for any substantive proposition . . . .")]. Any reference to material that was not in the trial record, Plaintiffs argue, was not substantive, as the twenty-one

sources were simply included in an appendix with his report. [FWK 350-1 at 21]. But, even if Amiji only relied on five of the twenty-one sources, he relied on them at great length. [FWK 385-1 at 11 n.30 (providing a list of twenty-four instances in which Amiji relies on expert testimony that was not submitted to the trial court)]. Plaintiffs argue, however that, though the five specific documents relied upon in Amiji's report were not submitted into evidence, "the substantive information contained therein *was* presented to the factfinder via testimony in open court by each of the experts." [FWK 350-1 at 22]. Amiji has therefore said that his opinions would not change if limited to the trial testimony. [FWK 325-177 ¶ 6 ("My opinion remains that, whether limited to the litigation record as Dr. Klibanov views it or encompassing the expert reports and other materials before the court prior to trial, Shire failed to show that fumaric acid in Actavis's ANDA satisfies or functions as element (c); Shire therefore could not meet its burden under any standard.")].

In his expert report in this matter, Cima similarly relied on his own expert report from the Shire-Actavis lawsuit, which was not submitted to the trial court. [FWK 325-178 ¶ 16 ("I restate and affirm my earlier analysis and conclusion of these questions from the Actavis Litigation. Much of the report that follows is produced verbatim or nearly verbatim from the earlier report.")]. Cima bases some of his analysis of the obviousness of Intuniv's patent claims on a patent that was never put before the trial court, the '452 patent. [FWK 325-178 ¶¶ 98–106]. Plaintiffs admit the '452 patent was not before the trial court, but argue that the patent was "consistent with but unnecessary to his conclusions" at the trial court. [FWK 350-1 at 12]. Specifically, Cima found that the twenty asserted claims in the Shire-Actavis lawsuit were anticipated or obvious in light of one or more prior art references. For each claim, Cima identified multiple prior art references that made the claim obvious or apparent. Therefore, even

if Cima considered a patent that was not put before the trial court, Plaintiffs argue, that patent is irrelevant to his analysis. [FWK 350-1 at 12–13]. Cima, however, references the '452 patent in every invalidity opinion in his expert report. See [FWK 325-178 ¶¶ 98–106].

Plaintiffs advocate that, if the Court finds Cima and Amiji's reliance on evidence outside of the trial record inappropriate, they "should be permitted to testify as to the numerous other prior art references which anticipate and/or render obvious each of the asserted claims of the Shire patents." [FWK 350-1 at 19]. The Court agrees. Unlike Klibanov, who was asked to evaluate the strength of Shire's case before Judge Andrews, Amiji was asked to give his opinion "as an objective, scientific matter" on whether the Actavis ANDA product infringed on Shire's patent claims. [FWK 325-177 ¶ 4]. Therefore, Amiji is free to testify as to his objective, scientific opinion. If, however, he attempts to opine as to the likelihood of success at the trial, or what Judge Andrews may have decided based on the record before him, Amiji's testimony shall be stricken as inappropriate. Defendants are free to make clear on cross examination that Amiji was not asked to opine as to the likelihood of success in the underlying litigation. Similarly, Cima will be permitted to testify as to whether the patents were "anticipated and/or obvious in light of the prior art existing at the time of the filing," [FWK 325-178 ¶ 15], but will not be permitted to rely on matters outside of the trial record to opine as to the likelihood of success in the underlying trial. Alternatively, both experts may testify as to the likelihood of success but must limit their testimony to evidence that was before Judge Andrews.[6] The motions to exclude the testimony of Amiji and Cima, [FWK 337; Picone 254], are therefore GRANTED in part and DENIED in part.

[6] To the extent that Thomas relies on Amiji and Cima's testimony in reaching his conclusion that Actavis was likely to succeed on the merits, beyond the 95% statistic that has already been excluded, such testimony must likewise be excluded.

C. Expert Testimony Concerning the Shire-Actavis Agreement

A generic manufacturer seeking FDA approval must certify that it will not infringe on a brand manufacturer's patents. 21 U.S.C. § 355(j)(2)(A)(vii). One way to accomplish this is for the generic manufacturer to "certify that any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale' of the drug described in the [ANDA]." Actavis, 570 U.S. 135, 143 (2013) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(V)). The Hatch-Waxman Act provides an incentive for generics to enter the market by providing a 180-day period during which "no other generic can compete with the brand-name drug." In re Loestrin, 814 F.3d at 543 (quoting Actavis, 570 U.S. at 143). "That said, the generic manufacturer may still face competition from a generic version of the drug produced by the brand manufacturer, also known as an authorized generic ("AG") at any time, including during the exclusivity period." Id. Therefore, both parties have provided a number of experts to testify as to whether the Shire-Actavis agreement contained a "No-AG Agreement," implicit or explicit, meaning an agreement not to launch an authorized generic during the exclusivity period, and whether Shire was even in a position to pursue an AG during Actavis's period of exclusivity.

1. Motion to Exclude in Part the Testimony of Harsha Murthy

The DPPs move to exclude certain opinions expressed by Shire's expert Harsha Murthy ("Murthy"), including those concerning the factors that pharmaceutical companies consider when deciding whether to launch an AG in response to a generic entering the market and whether Shire could have launched an AG version of Intuniv on its own. [FWK 298 at 1]. The IPPs subsequently moved to join the motion. [Picone 237]. Murthy is a senior pharmaceutical executive, currently serving as Managing Partner of Peak Pharma Commercial Partners, LLC, an investment fund that specializes in acquiring products that are near the end of their patent life or have generic competition. [FWK 301-72 ¶ 3].

Murthy provides and then relies on a list of eight factors that he believes pharmaceutical companies consider when deciding whether to launch an AG in reaching the conclusion that "a reasonable brand pharmaceutical company does not always, or necessarily, launch an AG during the generic first-filer's 180-day exclusivity period." [FWK 301-72 ¶ 16a]. This is in opposition to Plaintiffs' expert, Michael Johnson ("Johnson"), who testifies that brand companies have a large incentive to distribute their own authorized generics in response to a first-to-file ANDA generic, like Actavis. Murthy's factors are: "(i) the projected size of the brand and generic markets; (ii) the effect of the number of generic entrants on projected AG profitability; (iii) the expected gross-to-net [] sales ratio for the AG; (iv) the potential ability to maintain sales on the brand product; (v) the brand company's third-party relationships; (vi) the ability of generic entrants to supply the market; (vii) the effects of the launch on any pending litigations; and (viii) any 'life-cycle' plans for the brand product." [Id.].

"Expert testimony on industry standards is common fare in civil litigation." Levin v. Dalva Bros., 459 F.3d 68, 79 (1st Cir. 2006). Still, an expert who gives "little indication that his opinion was based on general industry customs and practices" cannot show that his proffered opinion is based on "sufficient facts or data." Pelletier v. Main St. Textiles, LP, 470 F.3d 48, 55 (1st Cir. 2006); see also McGovern ex rel McGovern v. Brigham & Women's Hosp., 584 F. Supp. 2d 418, 426 (D. Mass. 2008) ("While an expert may . . . testify solely on the basis of experience, he 'must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how the experience is reliably applied to the facts.'" (quoting Brown v. Wal-Mart Stores, Inc., 402 F. Supp. 2d 303, 308–09 (D. Me. 2005))).

Judge Zobel has found that expert opinions concerning "what questions would be addressed" and what "would have been considered" by a pharmaceutical company's decision-

makers to be impermissible. Organon USA Inc., 2015 WL 10002943, at *4. In that case, Judge Zobel explained:

> First, they are entirely unmoored from the relevant context. [The expert] does not explain who would address the questions or who would consider the information that he raises. Second, he does not explain the methodology that he used to decide what questions would be addressed and what would have been considered. He merely relied upon his "experience . . ." to provide the basis for his testimony. He offers no explanation of how his experience leads to his conclusions, as Daubert and Rule 702 require. By merely prefacing each of his opinions with a reference to his "experience," he asks the court (and, presumably, the jury) to "take his word for it," which the rules of evidence do not allow him to do.

Id. (emphasis omitted). Defendants argue that Judge Zobel only excluded the testimony because the witness in that case was unqualified. [FWK 363-1 at 10].

Judge Zobel was explicit in explaining that "what [wa]s lacking from [the expert's] background [wa]s direct experience in the pharmaceutical industry," noting that the expert "ha[d] not worked for a pharmaceutical company, nor any other company in the healthcare industry . . . . This hardly makes him qualified to testify about what 'companies in the health care industry . . . would have reasonably believed,' . . . ." Id. at 3. Still, Judge Zobel also went on to consider those portions of the expert's testimony which he was qualified to offer. Id. ("Although [the expert] is qualified to offer the other opinions in his report, that does not end the court's inquiry. All of the opinions in [the expert's] report must meet Daubert's exacting standards of reliability, which require more than subjective belief or unsupported speculation." (internal quotation marks and citations omitted)). Judge Zobel explained that, despite the fact that the expert was otherwise qualified to offer the testimony, the expert could not offer testimony as to what regulators "would have reasonably believed" because "he d[id] nothing more than rely on his prior employment . . . to review the facts of this case and speculate about how 'regulators' would have reacted to that evidence." Id. at 4. In addition, she noted that the expert "use[d] no testable methodology to arrive at his conclusions as to what regulators might have reasonably

believed" and "d[id] not explain how his experience [led] to the conclusions that he reache[d], why his experience offer[ed] a sufficient basis for his opinions, or how his experience could reliably be applied to the facts . . . ." Id. at 4.

Other courts, however, have specifically found that Murthy is qualified to testify as to what pharmaceutical companies consider when launching new products. See Lidoderm, 296 F. Supp. 3d at 1180–81 ("Murthy's opinions on what pharmaceutical executives consider with respect to at-risk launch fall reasonably within Murthy's experience in the industry, and his opinions about whether a reasonable company in Watson's position would have launched at-risk (based on his understanding of the disputed facts, light of the record evidence he reviewed), are also permissible."). The question before the Court is therefore whether Murthy's experience is sufficiently related to his enumerated factors, such that he can opine as to whether a reasonable company would have considered those factors in deciding whether to launch an AG.

In this case, Murthy was providing context for why a brand company might decide not to launch an AG in response to Plaintiff's expert Johnson's claim "that, absent the Actavis settlement, '[a] reasonable brand pharmaceutical company *in Shire's position* would have been willing and incentivized to introduce an authorized generic Intuniv product.'" [FWK 325-55 ¶ 8 (quoting 325-54 ¶ 4)]. Although Murthy's factors sound reasonable, he does not provide any explanation as to how he arrived at those specific factors, beyond a general reference to his previous experience. Murthy will be permitted to testify as to why his previous experience leads him to believe that a reasonable company would not necessarily introduce an AG and, instead, would consider a number of factors in determining whether to launch an AG. See [FWK 301-72 ¶ 27 ("I disagree with the conclusion in the Johnson report that a reasonable brand pharmaceutical company as a matter of course would launch an AG upon the launch of a first-

filer's generic product. To the contrary, based on my own experience as a pharmaceutical executive who has been directly involved in the discussions and planning as to whether and when to launch an AG, I know that the decision to launch an AG is a complex one and . . . does not automatically occur when a generic competitor first enters the market, even if the generic is entering the market as the lone generic during its first-filer 180-day exclusivity period. Indeed, brand pharmaceuticals companies choose, for a number of good reasons, not to launch an AG product in response to generic competition.")]. He may also testify about the specific factors that a reasonable brand company might consider, as long as he lays a proper foundation for those specific factors, including adequately explaining why his previous experience leads him to consider each of those individual factors. See, e.g., Lidoderm, 296 F. Supp. 3d at 1180–81 n.44 (permitting Murthy "to testify as to what 'a reasonable' company would have done when faced with the (disputed) facts in this case" but not about what the parties actually knew). Plaintiffs may object if Defendants fail to provide the necessary foundation.

Murthy next claims that a reasonable company in Shire's position could have launched an AG on its own, such that it would not require distribution through a third-party generic drug distributor. [FWK 301-72 ¶ 59]. Plaintiffs argue that Murthy fails to provide a single example of a brand drug that could launch an authorized generic without a generic distribution partner. [FWK 307 at 13]. Yet, Murthy includes a lengthy discussion of exactly such examples. See [FWK 301-72 ¶¶ 66–78 (providing examples of agreements involving Protonix, Actiq, Flonase, and Amrix)]. Still, Plaintiffs argue, even if a generic company could hypothetically launch its own AG, Murthy provides no evidence that Shire specifically could have done so. [FWK 307 at 13]. In fact, Plaintiffs argue, Shire had an agreement with Actavis that Shire would not "authorize or license a Third Party to market or sell AG product." [Id.]. Defendants maintain

that "market or sell" is a term of art within the industry, such that "[n]othing in Mr. Murthy's opinion is an admission of any kind concerning the use of any particular distribution arrangement under the Shire-Actavis License Agreement . . . ." [FWK 363-1 at 17–18]. Plaintiffs' arguments go to the weight of the testimony rather than its admissibility. It is clear that Murthy is qualified to offer his opinion that Shire was in a position to offer an AG and, even if the contract contained language that Shire would not authorize or license a third party to market or sell an AG, he is permitted to testify that Shire was itself in a position to market or sell an AG.

The motion to exclude Murthy's testimony, [FWK 298], is therefore GRANTED in part and DENIED in part. If Murthy is able to provide the necessary foundation and adequately explain why his specific previous experience leads him to consider each individual factor that a brand company might consider in deciding whether to launch an authorized generic, his testimony regarding such factors will be permitted. Plaintiffs are free to object as to whether he has provided sufficient foundation and question his experience on cross examination.

2. Motion to Exclude in Part the Testimony of William Zoffer and Dr. Iain Cockburn

Plaintiffs next move to exclude testimony from Shire's experts William Zoffer ("Zoffer") and Dr. Iain Cockburn ("Cockburn"), which concerns their opinions (1) that a reasonable brand pharmaceutical company can justify a reverse-payment settlement in order to avoid litigation, (2) as to why Shire might have settled, (4) on the viability of a post-settlement Intuniv AG launch, and (4) on the legal interpretation of the settlement agreement. [FWK 299 at 1]. The IPPs subsequently moved to join the motion. [Picone 237].

Zoffer has worked in the pharmaceutical industry for nearly thirty years, including working as a senior executive at GlaxoSmithKline. [FWK 301-102 ¶ 2]. Cockburn is a

professor at Boston University's Questrom School of Business, where he specializes in the pharmaceutical industry. [FWK 301-104 ¶ 1].

Plaintiffs first argue that Zoffer and Cockburn should not be permitted to testify regarding whether the settlement was justified in order to avoid litigation risk to Shire's patent monopoly. [FWK 308 at 7]. Under the Supreme Court's analysis in Actavis, once a plaintiff has made a prima facie showing that a settlement has anticompetitive effects, the burden shifts to the defendant to demonstrate the procompetitive benefits of the settlement. 570 U.S. at 157–58. The Supreme Court has explained, however, that a settlement cannot be justified by a patent holder's use of "monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement." Id. at 156.

Plaintiffs argue that, contrary to the Supreme Court's guidance in Actavis, Zoffer and Cockburn impermissibly cite litigation risks as justification for Shire's reverse payment. [FWK 308 at 8]. The Eastern District of Pennsylvania has explained that

> opinions that the reverse payments were made to avoid [the patent holder's] "litigation uncertainty"—that is, the risk of [the patent holder] losing the infringement litigation against the Generic Defendants and the . . . patent being declared invalid or not infringed—[are] not relevant for the purposes of explaining or justifying the reverse payments.

King Drug Co. of Florence, Inc. v. Cephalon, Inc. ("Provigil"), No. 06-cv-01797, 2015 WL 5783603, at *8 (E.D. Pa. Oct. 5, 2015); see also King Drug Co. of Florence v. SmithKline Beecham Corp., 791 F.3d 388, 411 (3d Cir. 2015) (finding that the argument that a settlement was "justified" by "the removal of the uncertainty created by the dispute" was "in tension with Actavis in that, without proper justification, the brand cannot pay the generic simply to eliminate the risk of competition").

Defendants argue that Zoffer and Cockburn's testimony is not being offered to provide a procompetitive justification for the settlement agreement under the burden-shifting analysis, but

is instead offered to demonstrate that there was no anticompetitive no-AG agreement. [FWK 361-1 at 8]. In other words, Defendants are providing the experts at step one to rebut Plaintiffs' prima facie showing that the settlement had anticompetitive effects. Defendants further argue that Plaintiffs' argument is disingenuous, when they themselves rely on experts whose opinions are based on "the totality of the facts and circumstances and the context of the negotiations," to discuss whether the settlement agreement, in context, suggests an anticompetitive agreement. [FWK 361-1 at 10 (emphasis omitted)].

The Court finds that the testimony is admissible for the purpose of establishing that there was not a no-AG agreement within the Shire-Actavis settlement. Unlike the cases relied upon by Plaintiffs, which concern cases in which there was an explicit no-AG agreement, Plaintiffs in this case argue that there was an implicit no-AG agreement, despite the settlement's explicit provision that Shire would be permitted to produce an AG. Therefore, Zoffer and Cockburn may testify as to why a reasonable party might settle a case in order to avoid litigation expenses, but, they may not testify that any alleged no-AG agreement was actually justified because it avoided litigation expenses.

Second, Plaintiffs argue that Zoffer's testimony concerning what Shire's settlement negotiators might have been thinking at the time of settlement should be excluded. [FWK 308 at 10]. Zoffer analyzes a summary of negotiations provided by Shire's general counsel and, for each sentence, provides an explanation as to what the parties were hoping to convey in the settlement. [FWK 308 at 11]. Judge Saylor has previously cautioned, and this Court agrees, that "[n]o level of expertise or experience will make an expert witness a mind-reader." Holmes Group, Inc. v. RPS Prods., Inc., No. 03-cv-40146, 2010 WL 7867756, at *5 (D. Mass. June 25, 2010).

Defendants maintain that Zoffer is not offering testimony about what the parties actually believed, but is instead opining on what a reasonable brand company would have interpreted under the circumstances. [FWK 361-1 at 15]. Such testimony has been permitted. See, e.g., In re Solodyn, No. 14-md-02503, 2018 WL 734655, at *2–3 (D. Mass. Feb. 6, 2018) (finding that an expert could not be permitted to testify regarding a party's "actual state of mind," but allowing experts to "opine about how a reasonable company sitting in [the party's] shoes may analyze the business context"); Provigil, 2015 WL 5783603, at *6 (permitting experts to testify when the "analyses [we]re largely derived from the economic information available to [d]efendants at the time of the settlement agreements, and those experts opine[d] on what a rational, objective actor would have considered in light of that information").

Zoffer, however, relies on email communications between Shire and Actavis to make a final determination as to whether the parties had agreed to a no-AG agreement. See [ECF No. 301-102 ¶ 121 ("Based on the parties' conduct—this continued sparring at a very late stage—I conclude that they were not operating with a tacit understanding that Shire would not participate in the market with an AG."); id. ¶ 110 ("Actavis responded to the proposal, apparently still very much animated by a genuine belief that Shire's retained right to participate in the market via an AG represented a significant business opportunity for Shire and a genuine competitive threat. The jousting, and the expenditure of time and energy over Shire's retained AG rights, thus continued.")]. Because such statements go beyond an opinion regarding what a reasonable company would have believed and instead try to elucidate the mental states of the parties, they must be excluded. Though Zoffer is free is testify as to what a reasonable party would hope to achieve through a settlement, he may not testify as to the subjective understandings of the

parties. To the extent his testimony goes beyond explaining how a reasonable party would act, it will be excluded.

Third, Plaintiffs argue that Zoffer's testimony should be excluded insofar as he claims that Shire could have distributed an AG. [FWK 308 at 18]. Here, Plaintiffs make essentially the same argument as those concerning Murthy, namely that Zoffer has failed to point to any specific experience with distributing an AG through the avenues he claims were available to Shire, and instead relies only on his general experience. [Id. at 18–19]. The First Circuit, however, has explained that, so long as an expert is generally "qualified . . . by knowledge, skill, experience, training, or education," Fed. R. Evid. 702, he "need not have had first-hand dealings with the precise type of events at issue," Microfinancial, Inc. v. Premier Holidays Int'l, Inc., 385 F.3d 72, 80 (1st Cir. 2004). Therefore, Plaintiffs' argument goes more "towards the weight of his testimony rather than his ability to testify as an expert." Perez-Garcia v. P.R. Ports Auth., No. 08-cv-01448, 2012 U.S. Dist. LEXIS 191575, at *11–12 (D.P.R. July 5, 2012) (finding that a mechanical engineering expert was qualified to testify about the design of golf carts, despite the fact that he had no experience with golf carts specifically).

Finally, Plaintiffs argue that Zoffer's testimony concerning the legal obligations under the settlement agreement, which includes interpreting provisions of the agreement, is inadmissible because he seeks to testify as to legal determinations. [FWK 308 at 20]. "The question of interpretation of [a] contract is for the jury and the question of legal effect is for the judge." SEC v. Goldsworthy, No. 06-cv-10012, 2008 WL 2943398, at *4 (D. Mass. Jan. 3, 2008). Again, Defendants argue that this is disingenuous, as Plaintiffs' own experts seek to testify about their interpretation of the settlement agreement, including whether it contained a no-AG agreement. [FWK 361-1 at 24]. Defendants maintain that Zoffer's testimony is permissible to respond to the

contention that a reasonable company would not understand the settlement agreement to mean that it was agreeing not to produce or distribute an AG. [Id. at 24–25]. Defendants claim that he therefore offers his expert opinion on the trade practices and custom that a reasonable company would employ in understanding the agreement. See, e.g., Keegan v. Steamfitters Local Union No. 420 Pension Plan, 67 F. App'x 744, 750 (3d Cir. 2003) ("[E]vidence of trade practice and custom does not trump other canons of contract interpretation, but rather cooperates with them."); Manhattan Re-Ins. Co. v. Safety Nat'l Cas. Corp., 83 F. App'x 861, 863 (9th Cir. 2003) (finding that an expert testifying about contract drafting customs and practices "did not improperly testify about the legal interpretation of contract clauses").

In this case, Zoffer seeks to testify as to how the contract should be interpreted. See, e.g., [FWK 301-102 ¶ 150 ("[M]y opinion is that the injunctive language of Section 8.8.2 presented no impediment or disincentive to Shire's exercise of its valuable retained AG rights. . . . [N]o reasonable brand company would interpret the remedial provisions as an impediment to the right that Shire had negotiated to participate in the market with an AG when Actavis launched its generic Intuniv product."); id. ¶ 158 (explaining that Shire's retaining the right to market an AG product "gave Shire a valuable opportunity to participate in the market with its own AG during Actavis's first 180-days of marketing its generic Intuniv product" which Zoffer interprets to "include[] the possibility of commercializing an AG with assistance from outside organizations or contract service providers with AG experience, or in the alternative, commercializing it completely 'on its own'")]. "Absent any need to clarify or define terms of art, science, or trade, expert opinion testimony to interpret contract language is inadmissible." Goldsworthy, 2008 WL 2943398, at *4 (quoting N. Am. Specialty Ins. Co. v. Myers, 111 F.3d 1273, 1281 (6th Cir. 1997)); see also Chow v. Zimny, No. 10-cv-10572, 2014 WL 4964408, at *1 (D. Mass. Sept. 30,

2014) (finding that an expert could not testify concerning how a reasonable party would have interpreted a contract in order to establish reliance in a fraud case). Therefore, to the extent that Zoffer seeks to testify as to how the contract should be interpreted, such testimony must be excluded.

The motion to exclude the testimony of Zoffer and Cockburn, [FWK 299], is therefore GRANTED in part and DENIED in part.

3. Motion to Exclude Thomas McGuire

Defendants move to exclude testimony from Plaintiffs' expert Dr. Thomas McGuire ("McGuire") to the extent that he opines that (1) the Shire-Actavis settlement operated as "an implicit No AG agreement," (2) Shire made a large and unexplained reverse payment to Actavis, (3) Actavis believed that Shire would not launch an AG, (4) a large and unexplained payment necessarily means that there was a delay in generic entry, and (5) alternative entry dates mean that the parties would have entered into a hypothetical no payment settlement agreement. [FWK 329; Picone 246]. McGuire is a professor of health economics at Harvard Medical School. [FWK 325-39 ¶ 5].

First, McGuire claims that "[t]he Shire-Actavis agreement contained an implicit no-authorized generic (no-AG) provision that ensured Shire would withhold the launch of an AG version of generic Intuniv, which would have competed with Actavis upon Actavis' generic entry. . . ." [Id. at ¶ 4]. Defendants argue that, in arriving at his position, McGuire analyzed how Shire would have understood the 25% royalty agreement, but failed to consider "how a reasonable company in *Actavis's position* would have viewed the 25% royalty in comparison to how it would have forecast Shire's profits from selling its own AG." [Picone 247-1 at 9]. In other words, Defendants maintain that McGuire failed to consider what Actavis would have thought of the settlement agreement. Defense expert Dr. Sumanth Addanki conducted an

empirical analysis of how a generic company in Actavis' position would have understood Shire's incentives and determined that a generic "would rationally have concluded that Shire would have only needed to obtain about 35 percent of the total sales of generic guanfacine ER during the generic firm's 180-day exclusivity period for it to be more profitable for Shire to sell an Intuniv AG than to not sell an AG and collect royalties instead." [FWK 325-29 ¶ 33].

Plaintiffs respond that McGuire did not need to engage in an empirical analysis to determine what a party in Actavis' position would have thought, as "record evidence illustrates how Actavis *actually* viewed the no-AG promise." [FWK 353-1 at 12]. Specifically, according to McGuire, Actavis records suggest that, before the settlement agreement, the company anticipated competition with an authorized generic. [FWK 325-39 ¶¶ 113–14]. After the settlement, however, Actavis records suggest that the company thought it would enjoy market exclusivity in the generic market for the entirety of the 180-day period. [Id.].

Defendants argue that it is improper for McGuire to testify as to what Actavis actually believed, because an expert may only testify as to what a reasonable party in Actavis' position would have done. [FWK 376-1 at 6–7]. See, e.g., United States ex rel. Dyer v. Raytheon Co., No. 08-cv-10341, 2013 WL 5348571, at *12 (D. Mass. Sept. 23, 2013) ("As the First Circuit has held in the criminal context, a party may not use an expert to 'bolster the credibility of [its] fact witnesses by mirroring their version of events.'" (quoting United States v. Montas, 41 F.3d 775, 784 n.4 (1st Cir. 1994))). "Experts are asked to testify to opinion rather than fact. While the difference between fact and opinion is often merely a difference of degree, the closer the purported 'expert' comes to testify[ing] about the very facts at issue in the case, the more that testimony must be scrutinized." Tuli v. Brigham & Women's Hosp., Inc., 592 F. Supp. 2d 208,

212 n.4 (D. Mass. 2009). To the extent that McGuire seeks to testify as to what Actavis actually understood, such testimony must be excluded.

Second, Defendants argue that McGuire should not be permitted to testify as to Shire's alleged large and unexplained reverse payment to Actavis. [FWK 247-1 at 15]. In support of his opinion, McGuire relies on the "Actavis Inference," which stands for the proposition that a reverse payment permits an inference that the parties agreed to a delay. See [FWK 325-39 ¶ 75]; see also Actavis, 570 U.S. at 158. According to McGuire,

> the logic of the inference goes like this: The litigation (competitive) route yields an expected profit to the brand, recognizing that the patent may or may not be found by the court to be valid and infringed. This is the expected profit associated with following through with litigation. Litigation requires the brand to pay its litigation costs. If the reverse payment exceeds any avoided litigation costs, we can infer that the brand must be getting higher profits from the settlement than it would with litigation. The only way for the brand's profits to be greater through a reverse payment settlement than through continued litigation is if the length of the monopoly retained by the brand under the reverse payment settlement is greater than the length of the monopoly it could expect to retain by continuing to litigate through trial and appeals.

[FWK 325-39 ¶ 75]. In this case, "Defendants acknowledge that, under Actavis, proof of a large and unexplained reverse payment *may* support an inference that the payment was offered to reduce the risk of earlier competition." [FWK 376-1 at 10]. During his deposition, however, McGuire argued that the Inference creates an if-then relationship, such that if there was a large payment, then there necessarily must have been an agreed-upon delay in entry. [Picone 247-1 at 19 n.58]. Such testimony is directly contrary to the First Circuit's holding in In re Nexium (Esomeprazole) Antitrust Litigation, in which the court held that the existence of a large payment does not necessarily prove delayed entry. 842 F.3d 34, 59–60 (1st Cir. 2016). Therefore, McGuire shall not be permitted to testify that a large payment necessarily means that there had to be a delayed entry.

Third, Defendants argue that McGuire makes the unsupported factual assertion that Actavis had decided to launch at risk. [Picone 247-1 at 17]. In coming to that conclusion, McGuire does not rely on any economic analysis, but instead reviews fact evidence, including Actavis emails. Plaintiffs maintain that it is permissible for McGuire to rely on Actavis's earnings expectations before the settlement agreement to extrapolate as to what Actavis believed its expected earnings would be if it was successful in the patent litigation in order to help determine whether the settlement agreement contained a no-AG agreement. [FWK 353-1 at 24]. But, as Defendants point out, McGuire's testimony regarding this issue appears to be an attempt to smuggle in a highly contested fact—whether Actavis did in fact intend to launch at risk—through an expert. [FWK 376-1 at 13]. Such testimony is inappropriate and must be excluded. Thus, McGuire is free to use factual evidence to arrive at a conclusion as to what a reasonable company in Actavis' position would have done given the financials, but he may not rely on Actavis' own records to testify that the company intended to launch at risk before entering into the settlement agreement.

McGuire also opines that there was evidence to suggest that Shire might launch a line extension of Intuniv and migrate sales to the new product in order to ensure that it had a longer period of exclusivity, also known as "product hopping." [FWK 325-4 ¶ 68]. Defendants argue that he does not have the technical expertise to opine as to whether Shire actually could have launched such a line extension product. [Picone 247-1 at 18–19]. Plaintiffs maintain that his testimony is not meant to suggest that Shire actually intended to create a line extension to extend its market exclusivity, but rather that Actavis would have considered that possibility when deciding whether to settle. [FWK 353-1 at 25]. Such an opinion, however, is divorced from McGuire's economic analysis. In fact, as Defendants note, "every projection he uses in his

analyses assumes that *no* product hop occurs, and he never applies any discount to those projections on the basis of a hypothetical product hop." [FWK 376-1 at 14]. Therefore, any reference to a potential product hop is excluded.

Lastly, Defendants argue that McGuire should not be permitted to testify about alternative licensed generic entry dates. [Picone 247-1 at 21]. McGuire believes that, based on the share of profits that the parties could have expected from a settlement and the likelihood that each party would prevail in the absence of settlement, the parties would have agreed to an entry date between June and October 2013. [FWK 325-39 ¶ 152]. First, McGuire's analysis depends on the parties agreeing that Actavis's likelihood of success at trial was between 90 and 100%. [Id.]. But, as Defendants point out, there is no evidence that Shire and Actavis agreed on the likelihood of success. [Picone 247-1 at 22]. In response, Plaintiffs argue that the percentages do not represent the parties' views on Actavis's likelihood of success at trial, but rather represent the actual likelihood that Actavis would have been successful, as represented by Plaintiffs' other expert, Thomas. [FWK 353-1 at 22]. Second, Defendants argue, it is possible that a generic would be so much better off from settling than continuing to litigate, that it would agree to a later entry date than McGuire's model would have predicted. [Picone 247-1 at 22]. For example, Defense expert Addanki calculates that the "probability of the generic firm winning the litigation would [have] had to [] exceed[] 96 percent for the expected economic gains from continuing the litigation to have exceeded" the economic gains from accepting a December 1, 2014 entry date. [FWK 325-29 ¶ 38].

The Court has found that Thomas's testimony as to Actavis having a 95% chance of success in the underlying litigation must be excluded, though he may testify that, based on his experience, it appeared that Actavis was likely to succeed, and to explain his opinion. Therefore,

McGuire may not rely on Thomas's 95% statistic in testifying as to possible generic entry dates. Further, though McGuire seeks to testify as to what the parties would have found to be a reasonable generic entry date, the 95% statistic does not represent the parties' own understanding of the likelihood of success at trial, which would be the relevant inquiry for determining what generic entry dates they might have otherwise considered. Insofar as McGuire is able, without relying on Thomas's 95% statistic, he may testify as to other reasonable dates for generic entry, but not the specific dates that the parties would have agreed to. See In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 174 (S.D.N.Y. 2018) (finding that an expert could not testify that the parties in an underlying litigation would have agreed to entry on a certain date, but allowing the expert to testify that "it would have been economically rational for both parties to enter into a no-pay settlement in a but-for world by specific dates, not that they necessarily *would have*" (emphasis in original) (internal quotation marks omitted)).

The motions to exclude McGuire's testimony, [FWK 329; Picone 246], are therefore GRANTED in part and DENIED in part.

4. Motion to Exclude Shashank Upadhye

Defendants next move to exclude the testimony of Plaintiffs' expert Shashank Upadhye ("Upadhye"), [FWK 335; Picone 252], a lawyer who previously worked at generic pharmaceutical manufacturing companies and whose current practice focuses on advising brand and generic companies about bringing products to market, [FWK 325-47 ¶ 2]. He seeks to offer testimony that Actavis and Shire's settlement negotiations did not reflect the practices of reasonable pharmaceutical companies.

First, Defendants argue that Upadhye is unqualified to give his opinion because, though he has experience representing pharmaceutical companies, he has never represented a brand company in negotiating of a Hatch-Waxman settlement. [Picone 253-1 at 7–8]. Plaintiffs

maintain that Upadhye has personally negotiated Hatch-Waxman settlements for generic companies and that the fact that he "sat on the generic side of the negotiation table does not mean he does not have a deep understanding of how reasonable brand companies settle Hatch-Waxman lawsuits with generic competitors." [FWK 357-1 at 12–13]. Upadhye is qualified to testify based on his previous experience negotiating Hatch-Waxman settlements. Defendants' argument goes to the weight of his testimony, not its admissibility.

Second, Defendants argue that Upadhye has not provided a methodology to support his opinions as to what a reasonable company would have done in the course of the Shire-Actavis settlement negotiations. According to Defendants, Upadhye's definition of a reasonable pharmaceutical company is circular, as he defines a reasonable company as one that follows the reasonable standards and practices of a pharmaceutical company. See [Picone 253-1 at 9–10 (quoting Upadhye's deposition); FWK 325-199 at 262–69 (providing Upadhye's deposition transcript, in which he defines a reasonable brand as "one that does not diverge from the reasonable standards and practices of pharmaceutical companies in negotiating Hatch-Waxman patent litigation settlements" but is unable to articulate those reasonable standards and practices)]. Plaintiffs argue that the jury should be permitted to rely on Upadhye's expertise regarding what a reasonable company would consider, but makes no argument concerning his methodology, instead relying on his qualifications. [FWK 357-1 at 15 ("A jury will likely not understand all of the business factors that may be addressed in the complex area of brand and generic Hatch-Waxman patent litigation settlement without expert guidance. Mr. Upadhye's business experience and his knowledge of industry best practices—what factors, and how *reasonable* companies would have considered those factors under the circumstances—makes him uniquely suited to help the jury answer the 'essential' question of why the defendants settled

with the terms that they did.")]. Like the other experts seeking to testify as to whether the Shire-Actavis settlement contained a no-AG agreement, Upadhye may testify, based on his own experience, as to how a reasonable party would or would not have entered into the Shire-Actavis agreement.

Upadhye additionally relies on Thomas's 95% statistic of likelihood of success as a fact, though it is unclear how a change in that percentage would affect his opinion. See [FWK 325-199 at 146–48 (Q: "If Thomas's opinion as to the likelihood of success changed, your opinions would change too, right? . . . . A: I mean, I can't answer that. I don't know what the changes would be or what changes [sic], and [it's] certainly beyond the scope of this report to hypothesize what could be an opinion based on changed facts and changed circumstances.")]. Having determined that Thomas cannot use the specific 95% statistic, Upadhye may not offer testimony that relies on that statistic.

Third, Defendants argue that Upadhye's testimony is unrelated to the facts of this case. For example, he cites a number of regulatory concerns and the potential for product hopping as being considerations that a reasonable company would consider in deciding whether to settle a case, but there is no evidence that there were such risks in the dispute underlying this case. [Picone 253-1 at 14–17]. Plaintiffs maintain that, just because those concerns did not materialize, does not mean that they were not concerns that a reasonable party would have considered in deciding whether to launch at risk. [FWK 357-1 at 13–14 ("That the risks, which Mr. Upadhye identifies a reasonable company would consider, did not actually occur, including that CarrierWave was not optimized in time for a product hop, are irrelevant to the obvious fact that Actavis could have *considered them as risks* for waiting to launch because such risks had

occurred in the past.")]. As with McGuire, any reference to potential product hopping is excluded.

Additionally, Upadhye discusses the parties' state of mind. For example, he claims that "Actavis was interested in allocating the market between them" and that "Actavis wanted . . . Shire to be unable to launch an AG and become a bona fide competitor, and it got that." [FWK 325-47 ¶ 80; FWK 325-48 ¶ 29]. Plaintiffs argue that Upadhye does not opine as to what the parties believed, but instead limits his analysis as to what reasonable parties would have believed in their positions. [FWK 357-1 at 23]. That position is unsupported by the Upadhye report itself, which clearly puts forth opinions concerning the intentions and mental states of Shire and Actavis during the underlying litigation and settlement dispute. See, e.g., [FWK 325-48 ¶ 29 ("Shire never intended to launch by itself or through an affiliate"); id. ¶ 137 ("Actavis and Shire believed the parties shared a mutual interest . . . ."); FKW 325-47 ¶ 107 ("Shire wanted to retain the right to launch an AG not because it expected to exercise that right, but only as a shield . . . from antitrust scrutiny."); id. ¶ 195 ("Mr. Boothe, a sophisticated executive at a sophisticated generic pharmaceutical company, wanted to launch as soon as the company obtained any inkling that the district court was going to rule in Actavis' favor."); id. ¶ 231 ("Actavis intended to and succeeded in bottlenecking the 180-day exclusivity for a prolonged, anticompetitive period. It was important during the settlement negotiations with Shire that the 180-day exclusivity [period] was preserved. This is why, when Shire learned that Actavis had obtained tentative approval, the Shire personnel exclaimed, 'Good News.'")]. Such assertions are clearly inappropriate expert testimony. See Holmes Grp., Inc., 2010 WL 7867756, at *5 ("An expert witness may not testify as to another person's intent. No level of experience or expertise will make an expert witness a mind-reader."); see also Solodyn, 2018 WL 734655, at *2–3 ("Inferences about the intent or

motive of parties or others lie outside the bounds of expert testimony . . . ."). For the reasons previously explained with regard to Zoffer's testimony, Upadhye may not testify as to the subjective beliefs and intentions of the parties. His testimony must therefore be limited to what a reasonable party would have thought in Actavis and Shire's positions.

Lastly, Defendants argue that Upadhye impermissibly makes a number of legal conclusions, including his interpretation of the settlement agreement, [Picone 253-1 at 20–23], and his resolution of disputed facts, [id. at 23–24], including describing facts that "the plaintiffs will seek to prove," [FWK 325-47 ¶¶ 23–30]. Plaintiffs maintain that "it is entirely appropriate Mr. Upadhye to offer expert testimony (including his explanations for these opinions) on the terms of the agreement as they relate to how reasonable pharmaceutical companies would have negotiated an agreement under the circumstances, reasonable pharmaceutical companies' considerations applied to the facts in this case, and whether and when a reasonable generic company would have launched at risk." [FWK 357-1 at 19–20]. Like Zoffer's testimony concerning the correct interpretation of the contract, Upadhye's testimony must be excluded to the extent that he seeks to testify about how the contract should be interpreted beyond explaining what a reasonable party would have intended and offering explanations of terms of art or other definitions that may be helpful for the jury.

The motions to exclude the testimony of Upadhye, [FWK 335; Picone 252], are therefore GRANTED in part and DENIED in part.

5. Motion to Exclude in Part the Testimony of Michael Johnson

Defendants next move to exclude portions of the testimony of Plaintiffs' expert Michael Johnson. [FWK 339; Picone 256]. Johnson opines that certain provisions of the Shire-Actavis settlement agreement are unreasonable and must have been the product of an undisclosed anticompetitive agreement. Johnson worked in the pharmaceutical industry for thirty-seven

years with Eli Lilly and Company, including working as the Vice President of Corporate Business Development where he led the group that determined whether Lilly should launch authorized generics of its brand products. [FWK 325-54 ¶¶ 11–14].

First, Defendants argue that Johnson is unqualified to offer these opinions. Johnson has stated that he has "not negotiated a Hatch-Waxman settlement agreement" and he has not negotiated a license or AG agreement. [FWK 325-187 at 102–03]; see [id. at 97 (explaining that he has not negotiated an agreement to distribute an AG, but has seen proposals)]. Johnson has, however, "negotiated at least dozens of license agreement[s], including in particular AG agreements to distribute an authorized generic version of a branded [] product." [FWK 325-54 ¶ 154]. As with Upadhye's testimony, Johnson is qualified to testify as to his expertise in negotiating licensing agreements. The fact that he has not specifically negotiated a Hatch-Waxman settlement agreement goes to the weight of his testimony, not its admissibility.

Second, Defendants claim that Johnson's opinions invade the province of the fact-finder by making conclusions about the ultimate legal and factual issues in the case. A "district court has broad discretion to exclude expert opinion evidence about the law that would impinge on the roles of the judge and jury." Pelletier, 470 F.3d at 54. "Expert testimony that 'merely tells the [factfinder] what result to reach is improper.'" QVC, Inc. v. MJC Am., Ltd., No. 08-cv-03830, 2012 WL 13565, at *2 (E.D. Pa. Jan 4, 2012) (alteration in original) (quoting Burger v. Mays, 176 F.R.D. 153, 156 (E.D. Pa. 1997)). Rule 704 of the Federal Rules of Evidence explicitly abolished the "ultimate issue" rule. That Rule explains that "an opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704. Still, though an expert may "testify as to ultimate issues," he may not "testify as to legal conclusions." Holmes Grp., Inc., 2010 WL 7867756, at *6.

In this case, Johnson plans to testify as to legal conclusions, including that "[n]o reasonable brand company in Shire's position would license valid intellectual property under these terms absent other considerations, such as a no-AG agreement," [FWK 325-54 ¶ 10], that "[i]n the absence of other provisions reflecting exchange of value, such as a no-AG agreement, none of [the license agreements] make[] any business sense," [id. ¶ 141], that "a reasonable brand company in Shire's position would have launched an authorized generic upon launch of a first-filer's generic product had it not entered into an anticompetitive settlement agreement," [FWK 325-55 ¶ 8], that "Shire's post-settlement decision-making process . . . was not guided by ordinary market forces but was instead driven by the anticompetitive terms of the settlement agreement between Shire and Actavis," [id. ¶ 10], among others. The Court agrees with the Sixth Circuit that expert testimony "that a price-fixing conspiracy existed" necessarily "embraces a legal conclusion which depends on antitrust doctrine," and therefore must be excluded. Hyland v. HomeServices of Am., Inc., 771 F.3d 310, 322 (6th Cir. 2014). Thus, to the extent that this expert offers legal conclusions, his testimony shall be excluded.

Defendants also argue that Johnson impermissibly discusses Shire's intentions and state of mind. [Picone 257-1 at 7]. Plaintiffs maintain that, though it would be impermissible for Johnson to offer his opinion of the Defendants' states of mind at the time of the settlement, he is permitted to "opine about how a reasonable company sitting in [the Defendants'] shoes may analyze the business context." [FWK 352-1 at 11–12 (quoting Solodyn, 2018 WL 734655, at *2) (emphasis omitted)]. Therefore, Johnson can render an opinion to the effect that "a reasonable brand company in Shire's position would have launched an authorized generic upon launch of a first-filer's generic product had it not entered into an anticompetitive settlement agreement." [Id. at 12–13 (quoting FWK 325-55 ¶ 8)].

Johnson also opines on what types of authorized generic options were permitted under the Shire-Actavis agreement, including a sales agency agreement or a wholesale agreement. "The question of interpretation of [a] contract is for the jury and the question of legal effect is for the judge. In neither case do [courts] permit expert testimony." Goldsworthy, 2008 WL 2943398, at *4 (second alteration in original) (quoting Marx & Co., Inc., v. Diners' Club, Inc., 550 F.2d 505, 508 (2d Cir. 1977)). In Goldsworthy, the court did not allow an expert to testify regarding contract interpretation. Id.; see also United States v. Lupton, 620 F.3d 790, 799–800 (7th Cir. 2010) (affirming the exclusion of expert testimony concerning the meaning of contract terms, which are "a subject for the court, not for testimonial experts"). Plaintiffs counter that Johnson is not offering a legal conclusion on the agreement, but instead an opinion based on his experience in the industry that "a reasonable brand company in Shire's position would not market or distribute AG product itself, either by approaching wholesalers or hiring consultants" and that Defense experts have "shoehorn[ed] . . . Sales Agency examples into a non-third-party label,'" when the examples "actually reflect a third-party distributor arrangement." [FWK 352-1 at 18–19 (quoting FWK 325-55 ¶ 58)]. As with the other experts opining on the meaning of the Shire-Actavis agreement, Johnson is free to testify as to what a reasonable party would have agreed to, based on his own experience, and what specific terms may mean, if they are too complicated for a jury and would benefit from his experience in the market. He may not, however, testify about what Shire and Actavis subjectively believed the contract to mean, or about what the contract objectively required, both of which are inappropriate topics for expert testimony.

Finally, Defendants maintain that Johnson's statements pertaining to the Shire-Actavis agreement are unsupported by any previous experience or methodology. Those statements

include that the agreement made no "business sense" and therefore must arise from "a no-AG" or some other "[ill]egitimate" agreement. [FWK 325-54 ¶ 141 ("In the absence of other provisions reflecting exchange of value, such as a no-AG agreement, none of this makes any business sense.")]. First, Defendants once again argue that Johnson is unqualified to offer such opinions, given that he has never participated in negotiating a Hatch-Waxman settlement agreement. [Picone 257-1 at 16]. Plaintiffs contend that Johnson is sufficiently qualified to offer his opinion on authorized generic agreements, even if his experience is outside of Hatch-Waxman settlements. [FWK 352-1 at 18]. Second, Defendants claim that Johnson has not offered any methodology for how he arrived at his conclusions. [Picone 257 at 2]. For example, Johnson believes that the 25% royalty rate is "well below the range of what a reasonable brand company would accept," but does not identify what a reasonable rate would be. [Id. at 13; FWK 325-54 ¶ 155]. He does, however, offer testimony that, in his experience, a generic company would pay 80–90% of its gross profits to the brand company on generic sales. [FWK 325-54 ¶ 155]. Therefore, this specific argument goes to the weight of the testimony, not its admissibility.

Johnson also believes that Shire's analysis concerning the launch of an AG was merely pretextual as it "involved nothing more than updating spreadsheets and drafting PowerPoint slides." [FWK 352-1 at 20 ("No reasonable brand company would consider Shire's purported efforts in 2014—which involved nothing more than updating spreadsheets and drafting PowerPoint slides—a serious effort." (quoting FWK 325-55 ¶ 45))]. Again, the argument is supported by Johnson's experience and Defendants may cross-examine on the issue.

The motions to exclude Johnson's testimony, [FWK 339; Picone 256], are therefore GRANTED in part and DENIED in part.

IV. CONCLUSION

Accordingly, the motion to exclude Bell, [FWK 296], is DENIED; the motions to exclude Starr and Baum, [FWK 331; Picone 248], are DENIED; the motions to exclude Fernandez's testimony, [FWK 341; Picone 258], are DENIED; the motion to exclude paragraphs 218, 219, and 222 of Klibanov's report, [FWK 297], is GRANTED; the motions to exclude Thomas's testimony, [FWK 333; Picone 250], are GRANTED in part; the motions to exclude the testimony of Amiji and Cima, [FWK 337; Picone 254], are GRANTED in part; the motion to exclude Murthy's testimony, [FWK 298], is GRANTED in part; the motion to exclude the testimony of Zoffer and Cockburn, [FWK 299], is GRANTED in part; the motions to exclude McGuire's testimony, [FWK 329; Picone 246], are GRANTED in part; the motions to exclude the testimony of Upadhye, [FWK 335; Picone 252], are GRANTED in part; and the motions to exclude Johnson's testimony, [FWK 339; Picone 256], are GRANTED in part.

SO ORDERED.

September 10, 2020

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE